(21)

No. 99-1257

Supreme Court, U.S.
FILED
SEP 6 2000
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IN THE

Supreme Court of the United States

CAROL M. BROWNER, ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY, *et al.*,
Petitioners,

v.

AMERICAN TRUCKING ASSOCIATIONS, INC., *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF *AMICI CURIAE* SENATOR ORRIN HATCH AND REPRESENTATIVE TOM BLILEY IN SUPPORT OF RESPONDENTS

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September 11, 2000

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

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QUESTION PRESENTED

Whether the Environmental Protection Agency's interpretation of Section 109 of the Clean Air Act, in conformity with *Lead Industries Ass'n* v. *EPA*, 647 F.2d 1130, 1148 (D.C. Cir. 1980), effects an unconstitutional delegation of legislative power?

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INTEREST OF *AMICI CURIAE* [1]

Amicus Orrin Hatch is a Member of the United States Senate from Utah, and *amicus* Tom Bliley is a Member of the United States House of Representatives from Virginia. *Amici* are both concerned that the Environmental Protection Agency's ("EPA") implementation of the Act is contrary to congressional will, undermines the separation of powers, and frustrates effective congressional and judicial oversight. Because EPA has been hamstrung by an erroneous judicial precedent that irrationally prevents the agency from considering the cost effectiveness of its regulations, and that provides no other constitutionally required intelligible principles to constrain the agency's discretion, EPA engages in a science charade wherein policy and economic judgments are masked as scientific determinations.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

This case involves a statutory provision that confers unusually broad administrative power. Under this Court's teaching, the statute—and the Agency's interpretation of its authority thereunder—must receive "separation of powers" scrutiny commensurate with the potential impacts on society.

On petition for review of the revised national ambient-air quality standards ("NAAQS") for particulate matter ("PM") and ozone set by the EPA pursuant to section 109 of the Clean Air Act ("Act"), the United States Court of Appeals for the District of Columbia held that "the construction of the Clean Air Act on which EPA relied in promulgating the

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[1] Pursuant to Rule 37.6 of the Rules of this Court, *amici* state that no counsel for any party authored this brief in whole or in part, and that Citizens for a Sound Economy has made a monetary contribution to the preparation and submission of this brief. The parties have consented to the filing of this brief. Letters evidencing such consent have been filed with the Office of the Clerk of this Court. *See* Sup. Ct. R. 37.3.

NAAQS at issue here effects an unconstitutional delegation of legislative power." Pet. App. 4a. The court declared that it was not enough that EPA had identified the factors it used in determining standards, for "EPA appears to have articulated no 'intelligible principle' to channel its application of these factors; nor is one apparent from the statute." *Id.* at 5a. Noting that there is no threshold concentration below which ozone and PM do not adversely affect health, that EPA has declined to read section 109 to require it to eliminate all health risks, and that the decisional factors listed by EPA "do not themselves speak to the issue of degree," *id.* at 7a, the court of appeals correctly held that "EPA lacks . . . any determinate criterion for drawing lines" and "has failed to state intelligibly how much is too much." *Id.* at 6a.

The court found no enlightenment in the agency preambles for the final rules, which amounted to little more than a showing "that EPA is applying the stated factors and that larger public health harms (including increased probability of such harms) are, as expected, associated with higher pollutant concentrations." *Id.* at 10a. The Agency's identification of relevant factors did not provide any intelligible principle limiting agency discretion; EPA's rationale "could as easily, for any non-threshold pollutant, justify a standard of zero." *Id.* at 11a. Cost-benefit analysis, the Court observed, would avoid such indeterminacy, but D.C. Circuit precedents "read § 109(b)(1) as barring EPA from considering any factor other than 'health effects relating to pollutants in the air.'" Pet. App. 15a (citing, *inter alia*, *Lead Indus. Ass'n* v. *EPA*, 647 F.2d 1130, 1148 (D.C. Cir. 1980)).[2]

[2] The Government suggests that the court of appeals wandered off into the constitutional thicket on its own by stating that the court "[r]el[ied] on a theory that the parties had not extensively briefed." U.S. Br. 15. To the contrary, the issue was amply briefed below. Not only was the issue raised by the "Small Business Petitioners," Pet. App. 5a, but *amici curiae* Senator Hatch (in the PM case) and Representative Bliley (in the ozone case) each submitted full-length briefs devoted to the nondelegation issue. In the ozone case, the Government moved to strike the Bliley brief, but its motion was denied. Order, No. 97-1441 (D.C. Cir. May 19, 1998). In the PM case, the Government requested, and was granted, additional pages to brief the nondelegation issue in response to the Hatch brief. Order, No. 97-1440 (D.C. Cir. June 25, 1998).

The court of appeals was thus forced to address the constitutional issue of nondelegation only because it was constrained to follow the erroneous circuit precedent of *Lead Industries*. As demonstrated in the brief of *amici curiae* in the companion case No. 99-1426 ("Hatch/Bliley Br."), the Clean Air Act does permit the EPA Administrator to consider cost-benefit analysis in setting NAAQS. Where Congress has not mandated a "zero risk" standard (as EPA concedes) and scientific evidence of public-health dangers is not itself determinative, cost-effectiveness (including cost-benefit balancing) is a necessary risk-management principle that guides and limits the Administrator's choice of a NAAQS that is "requisite to protect the public health" and "allow[s] an adequate margin of safety," 42 U.S.C. § 7409(b)(1). While Congress has made the fundamental choices about environmental regulation, it relies on the Administrator to determine the precise level of NAAQS based on her expert consideration of the best science, medical data, and *all* of the other relevant factors requisite to assure the public health is adequately protected.

Lead Industries's exclusion of cost-benefit balancing empowers the Administrator to regulate without limits. Unwilling to admit or surrender the unfettered discretion it exercises, EPA engages in "science charades" that mask inevitable cost-based decisions as science-based, and it effectively abandons—on covert grounds—the core Clean Air Act goal of NAAQS attainment. Hatch/Bliley Br. 25-30 (discussing negative implications for attainment of the President's $10,000 per ton cap on "implementation" costs).

Not only is the error of *Lead Industries* manifest, but the doctrine of avoidance of constitutional questions compels its rejection by this Court. The prohibition against delegation of legislative power committed exclusively to Congress by Article I is an indispensable element of separation of powers. In modern jurisprudence, the nondelegation doctrine plays a vital role as a canon of statutory construction by which this Court narrowly construes broad statutory grants of authority to supply meaningful and constitutionally necessary constraints on agency discretion. The decision below is thus right in line with this Court's application of the nondelegation doctrine subsequent to the era that produced *A.L.A. Schechter Poultry Corp.* v. *United States*, 295 U.S. 495, 537 (1935).

As this Court's precedents make clear, whether a given statutory delegation is an unconstitutional grant of arbitrary power to an agency depends critically on context. The Government and its supporters miss this point by mechanically citing the language of statutory delegations upheld by this Court in the past, without regard to the statutory and factual contexts defining limits for those delegations. The context for setting NAAQS under the Clean Air Act is fundamentally different because of the conceded indeterminacy of the relevant science and the unparalleled power the Administrator wields under section 109 over states, local governments, and the American public. The non-delegation decisions of this Court require a narrowing construction of administrative authority to ensure that such power is properly circumscribed.

Lead Industries extinguished intelligible principles that could constrain the Administrator's judgment in this context. The principle suggested by the Government and its supporters—that the Administrator has a mandate to protect the public health by setting NAAQS based only on scientific or medical evidence of health risks suffered by sensitive populations—does not in fact provide any decisional

principle to guide the Administrator in deciding which health risks she will abate and which she will tolerate. The Administrator has acknowledged that Congress did not intend NAAQS to be set at a level to eliminate all health risks, for that would be harmful to the country. Thus, EPA is essentially rationing public health protections: it has set the ozone and PM NAAQS at levels that will protect some populations from health impairment, but not others.

The Administrator purports to rely exclusively on science-based criteria in making those choices. But risk management, which is what the NAAQS provisions of the Act require, is not that simple. Under the *Lead Industries* regime, EPA is denied the measuring stick necessary to make comparative judgments about public-health impacts. As a result, EPA cannot forthrightly justify where it has drawn the lines of protection. *Lead Industries* thus leads to incoherence and science charades, as these rulemakings demonstrate. See *infra* at 26-29. Congress cannot be presumed to have delegated to the Administrator such massive power over American life without a rational principle to direct her judgments. See *FDA* v. *Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291, 1301 (2000). Under such a reading, the Administrator exercises an impermissible power, legislative in nature, to allocate health protections based on arbitrary (and not fully disclosed) factors.[3]

Section 109 is not unconstitutional simply because *Lead Industries* does not supply an intelligible limiting principle; rather, this Court's nondelegation jurisprudence requires that this Court, if at all possible, adopt an alternative construction

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[3] EPA's ozone rule fails to protect perhaps an additional 18,000 children from moderate or severe pain on inspiration without any basis in the scientific evidence to differentiate them from children who are protected. *See infra* at 28-29. If EPA has denied this protection on any basis other than balancing the overall benefits and costs to the public, its decisionmaking is illegitimate as well as arbitrary.

with limiting principles that deflect doubts about a statute's constitutionality. As the court below acknowledged, cost-effectiveness is an intelligible principle to guide the Administrator in allocating health care protection under the Act—indeed, it is the universally accepted principle of environmental risk management and line-drawing. Nothing in the statute prohibits the Administrator from considering cost-effectiveness, and, as argued in the companion case, the statutory text, structure, and history indicate that Congress intended the Administrator to take such factors into account. This Court should reject *Lead Industries* and hold that the Administrator may consider the cost-effectiveness of alternative standards where the science is inconclusive.

I. NONDELEGATION IS A VITAL PRINCIPLE OF SEPARATION OF POWERS THAT GUARDS AGAINST GRANTS OF ARBITRARY POWER TO THE EXECUTIVE.

A. Congress May Not Grant The Executive Branch (And The Executive May Not Usurp) Arbitrary Power Unbounded By Law.

Article I, section 1 of the Constitution grants "[a]ll legislative Powers" exclusively to Congress. See U.S. Const. art. I, § 1. "That Congress cannot delegate legislative power to the President is a principle universally recognized as vital to the integrity and maintenance of the system of government ordained by the Constitution." *Field* v. *Clark*, 143 U.S. 649, 692 (1892). This principle "ensures to the extent consistent with orderly governmental administration that important choices of social policy are made by Congress, the branch of our Government most responsive to the popular will." *Industrial Union Dep't, AFL-CIO* v. *American Petroleum Inst.*, 448 U.S. 607, 685 (1980) (Rehnquist, J., concurring in the judgment); *Loving* v. *United States*, 517 U.S. 748, 757-58 (1996). The nondelegation doctrine thus "prevent[s] Congress from forsaking its duties," even when it does not

encroach upon the prerogatives or impair the functioning of a coordinate branch. *Id.* at 758. "Abdication of responsibility is not part of the constitutional design." *Clinton* v. *City of New York*, 524 U.S. 417, 452 (1998) (Kennedy, J., concurring).

Nondelegation is not, however, strictly a matter of preventing one branch's exercise of functions properly belonging to another. This doctrine applies not only to circumstances where the executive is given the power to issue prospective rules with the force and effect of law (although such power is granted here), but also to the quintessentially executive function of administering a statute in a specific case.[4] All federal executive authority not independently derived from the Constitution must be granted by Congress, *Louisiana Public Service Commission* v. *FCC*, 476 U.S. 355, 374 (1986), and no officer may be given power unbounded by law. The fundamental concern in any kind of statutory delegation to the executive branch is whether it grants "arbitrary discretion," *Buttfield* v. *Stranahan*, 192 U.S. 470, 496 (1904); *Union Bridge*, 204 U.S. at 387; *Federal Radio Commission* v. *Nelson Brothers Bond & Mortgage Co.*, 289 U.S. 266, 282 (1933); *Schechter Poultry*, 295 U.S. at 537, whereby the executive acts as a law unto itself. See *Clinton*, 524 U.S. at 452 (Kennedy, J., concurring) (nondelegation is a vertical protection of the citizenry as well as a horizontal protection of the division of power among the

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[4] *See, e.g., Lichter* v. *United States*, 334 U.S. 742, 775-76 (1948) (authorization of administrative officials to renegotiate a wartime contract based on a determination that the contractor earned "excessive profits"); *American Power & Light Co.* v. *SEC*, 329 U.S. 90, 96-97 (1946) (authorization of SEC, after an opportunity for a hearing, to order a holding company to adopt a corporate structure that equitably distributes shareholder voting power); *Union Bridge Co.* v. *United States*, 204 U.S. 364, 367-68 (1907) (authorization of Secretary of War, after an opportunity for a hearing, to order a bridge owner to remove unreasonable obstructions to navigation).

branches). Congress has broad power to draw policy lines subject to the minimal constraints of legislative rationality, see *Vance* v. *Bradley*, 440 U.S. 93, 108 (1979) (permitting Congress to set mandatory retirement age of 60 for foreign service officers); *National Cable Television Ass'n* v. *United States*, 415 U.S. 336, 342 (1974), but the executive does not.

B. The Nondelegation Doctrine Has Emerged As An Important Canon Of Statutory Construction To Constrain Executive Power.

The essential inquiry in this Court's nondelegation jurisprudence is to ascertain when the executive discretion granted by Congress is arbitrary. Delegation of discretionary authority has long been recognized as a legitimate attribute of legislative power, see *Wayman* v. *Southard*, 23 U.S. (10 Wheat.) 1, 42 (1825); *Field* v. *Clark*, 143 U.S. 649, 693-94 (1892), and this Court has not hesitated to approve even " 'broad' standards for administrative action" that are "a reflection of the necessities of modern legislation dealing with complex economic and social problems." *American Power & Light*, 329 U.S. at 105 ("Necessity . . . fixes a point beyond which it is unreasonable and impracticable to compel Congress to prescribe detailed rules . . . ."); *Sunshine Anthracite Coal Co.* v. *Adkins*, 310 U.S. 381, 398 (1940). But even so, discretion, in Justice Cardozo's famous words, must be "canalized within banks that keep it from overflowing" and not "unconfined and vagrant." *Schechter Poultry*, 295 U.S. at 551 (Cardozo, J., concurring); *Touby* v. *United States*, 500 U.S. 160, 166 (1991) (the statute must "meaningfully constrain[] the [officer's] discretion"). Congress must fix the "primary standard," *Buttfield*, 192 U.S. at 496, against which executive action may be measured so that a court may " ' "ascertain whether the will of Congress has been obeyed." ' " *Skinner* v. *Mid-America Pipeline Co.*, 490 U.S. 212, 218 (1989) (quoting *Mistretta* v. *United States*, 488 U.S. 361, 379 (1989) (quoting *Yakus* v. *United States*,

321 U.S. 414, 426 (1944))); see also *Clinton*, 524 U.S. at 484 (Breyer, J., dissenting). In this Court's classic formulation, "[s]o long as Congress 'lays down by legislative act an intelligible principle to which the person or body authorized to act is directed to conform, such legislative action is not a forbidden delegation of legislative power.'" *Touby*, 500 U.S. at 165 (brackets omitted) (quoting *J.W. Hampton, Jr. & Co.* v. *United States*, 276 U.S. 394, 409 (1928)). Cf. *AT&T Corp.* v. *Iowa Utils. Bd.*, 525 U.S. 366, 388 (1999) (interpreting statute to require agency "to apply *some* limiting standard, rationally related to the goals of the Act").

Although this Court has struck down statutes as violating the nondelegation doctrine only in two 1935 decisions, *Panama Refining* and *Schechter Poultry*, the doctrine remains an important canon of interpretation employed to give "narrow constructions to statutory delegations that might otherwise be thought to be unconstitutional." *Mistretta* v. *United States*, 488 U.S. 361, 373 n.7 (1989). Thus, in *Kent* v. *Dulles*, 357 U.S. 116, 128-29 (1958), this Court invoked nondelegation principles to narrow a statute to deny the Secretary of State "unbridled discretion" to restrict the right of citizens to travel. See also *National Cable*, 415 U.S. at 342 (avoiding nondelegation problem by narrowing power of agency to assess fees). And, in *Industrial Union Department, AFL-CIO* v. *American Petroleum Institute*, 448 U.S. 607 (1980), a case strikingly parallel to this one, the Occupational Safety and Health Administration (OSHA) had interpreted its organic statute to permit it to promulgate workplace standards to regulate any health risks from dangerous substances. Noting that OSHA's construction suggested a grant of "unprecedented power over American industry" to an administrative agency to engage in "pervasive regulation limited only by the constraint of feasibility," *id.* at 645, a plurality of this Court narrowed the statute to empower OSHA to regulate only "significant" risks to health and safety. *Id.* at 642. Otherwise, this Court held, "the statute would make such a

'sweeping delegation of legislative power' that it might be unconstitutional under the [nondelegation doctrine]. A construction of the statute that avoids this kind of open-ended grant should certainly be favored." *Id.* at 646; see also *id.* at 672-76 (Rehnquist, J., concurring in the judgment) (voting to invalidate the statute as an unconstitutional delegation of legislative power).

C. The Arbitrariness Of A Grant Of Power Depends On Context.

As this Court's nondelegation precedents make clear, whether a statute delegates arbitrary power depends critically on context. *Lichter*, 334 U.S. at 785 ("Standards prescribed by Congress are to be read in light of the conditions to which they are to be applied."); *American Power & Light*, 329 U.S. at 104 (statutory standards are not to "be tested in isolation," but "derive much meaningful content from the purpose of the Act, its factual background and the statutory context in which they appear"); *Nelson Bros.*, 289 U.S. at 285; *New York Cent. Sec. Corp.* v. *United States*, 287 U.S. 12, 24 (1932); *National Broad. Co.* v. *United States*, 319 U.S. 190, 215-16, 219 (1943) ("*NBC*"); see also *Clinton*, 524 U.S. at 488 (Breyer, J., dissenting). The intelligible-principle rule is always the same, but the sufficiency of a given standard under that rule turns not just on the bare language of the statute, but on numerous factors specific to the statutory scheme. Thus, the arbitrariness of a delegation may depend upon the clarity of statutory purposes, *American Power & Light*, 329 U.S. at 105; *New York Central*, 287 U.S. at 24-25, the complexity of the subject matter of regulation, *NBC*, 319 U.S. at 219, the variability of factual conditions, *J.W. Hampton, Jr. & Co.* v. *United States*, 276 U.S. 394, 404-05 (1928); *United States* v. *Grimaud*, 220 U.S. 506, 516 (1911), the exigency of circumstances, *Touby*, 500 U.S. at 168; *Lichter*, 334 U.S. at 779-80, the nature of power being exercised and of the officer exercising it, *Loving*, 517 U.S. at 772; *United States* v.

Mazurie, 419 U.S. 544, 556-67 (1975),[5] past administrative practice, *Kent*, 357 U.S. at 127-28; *Lichter*, 334 U.S. at 777-78, 783, the presence of procedural safeguards, *Lichter*, 334 U.S. at 786-87; *Union Bridge*, 204 U.S. at 387, whether the regulation concerns government property or the public domain, *Grimaud*, 220 U.S. at 521; *Nelson Bros.*, 289 U.S. at 282, whether constitutionally protected rights are at stake, *Kent*, 357 U.S. at 128-29, and whether unusually broad administrative power is conferred, *Industrial Union*, 448 U.S. at 645-46; *Schechter Poultry*, 295 U.S. at 542; *Michigan* v. *EPA*, 213 F.3d. 663, 680-81 (D.C. Cir. 2000).

The Government and its supporters disregard the crucial element of context by mechanically citing broad language of delegation in statutes that have been upheld by this Court; they argue that, even under *Lead Industries*, the detailed prescriptions of section 109 cannot be unconstitutional in light of past decisions of this Court upholding standards such as the "public interest," "public convenience," justice and equity, and reasonableness. Cf. U.S. Br. at 22, 25; Mass Br. at 29, 35; see also Pet. App. 59a-60a (Tatel, J., dissenting in part). The cited cases, however, involved circumstances where there were ascertainable historical facts that could be found by the administrative or executive officer; the officer's judgment (whether embodied in an order or a generally applicable regulation) could be applied to those facts and tested by a court against reason and statutory purpose. The broad standards at issue in those cases related to administrative determinations based on the actual costs or conditions of a particular company or industry,[6] on historical

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[5] *Cf. Clinton*, 524 U.S. at 445 (noting special foreign-affairs context of *Field* v. *Clark*).

[6] *See Skinner*, 490 U.S. at 219-20 (imposition of fees on pipeline companies based on "reasonable relationship" to their specific volume-miles, miles, and revenues); *Lichter*, 334 U.S. at 785-86 (determination of "excessive profits" earned on a specific government contract based on cost investigation); *Yakus* v. *United States*, 321 U.S. 414, 420-21 (1944)

practices or exigencies of a specific industry,[7] or on narrowly defined and detailed factual investigation of a particular subject matter.[8] Because the statutory standards at issue were tethered to ascertainable facts and conditions, this Court has repeatedly stated that even broad standards such as the "public interest" are not "indefinite" given the context and the

(wartime fixing of maximum prices for commodities that are "just and equitable" after ascertainment of "prevailing prices" with adjustments for factors such as speculation, cost changes, and profit trends); *Federal Power Comm'n* v. *Hope Natural Gas Co.*, 320 U.S. 591, 600-01 (1944) (determination of "just and reasonable rate[s]" for a specific utility based on its cost structure); *Opp Cotton Mills* v. *Administrator of Wage Hour Div. of Dep't of Labor*, 312 U.S. 126, 144-46 (1941) (determination of minimum wages for classes of industry based on factfinding regarding competitive conditions and effect on employment); *Sunshine Anthracite Coal*, 310 U.S. at 397-98 (determination of maximum and minimum prices for coal based on prevailing costs-per-ton and market prices, with exemptions to ensure "fair return" or "fair value" for every mine); *American Power & Light*, 289 U.S. at 105 (determination of fairness of distribution of voting power of shareholders of a specific corporation); *New York Cent.*, 287 U.S. at 24-25 (determination of whether a specific railroad's acquisition of control of another's line is in the "public interest").

[7] *See NBC*, 319 U.S. at 217 (regulation of radio licensees); *Nelson Bros.*, 289 U.S. at 282 (same); *Interstate Commerce Comm'n* v. *Goodrich Transit Co.*, 224 U.S. 194, 214-15 (1912) (formulation of uniform systems of accounts to monitor common carriers by water); *Grimaud*, 220 U.S. at 515-16, 521 (authorization of regulations of "occupancy and use" for preservation of national forests, which persons use under an "implied license" from the Government).

[8] *See Union Bridge*, 204 U.S. at 386-87 (determining after hearing whether a particular bridge examined by the Army Corps of Engineers was an unreasonable obstruction to navigation); *Buttfield*, 192 U.S. at 494-95 (issuance of standards of "purity, quality, and fitness for consumption" based on expert rankings of imported teas); *Field*, 143 U.S. at 692-93 (suspension of free importation of articles after investigation as to whether exporting country imposed duties that were "reciprocally unequal and unreasonable").

statutory purposes. See, *e.g.*, *Nelson Bros.*, 289 U.S. at 285; *New York Cent.*, 287 U.S. at 24.[9]

D. Whether *Lead Industries* Is Inconsistent With The Nondelegation Doctrine Must Be Determined In Light Of The Statutory Context Of Scientific Indeterminacy And Vast Administrative Power.

The context of the Clean Air Act is fundamentally different from that of statutes reviewed in this Court's prior nondelegation decisions (except for *Industrial Union*) in two important respects. The first is the inherently subjective nature of regulatory science. As Sheila Jasanoff has documented, there has been a profound shift in administrative regulation from traditional factfinding and industry expertise to the "new" administrative agencies such as EPA engaged in "regulatory science." Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policy Makers* 40-45 (1990).[10] Regulatory science is different from rigorous research science; it is policymaking requiring "'predictions ... at the frontiers of science.'" *NRDC* v. *EPA*, 902 F.2d 962, 968 (D.C. Cir. 1990), *vacated in part on other grounds*, 921 F.2d

[9] Reasonableness, fairness, justice, equity, and the public interest are not lawless standards for fact-specific judgments; they are the foundational standards of the common law and equity. *Cf. Missouri* v. *Jenkins*, 515 U.S. 70, 129 (1995) (Thomas, J., concurring) (discussing historical conception that principles of equity do not grant " 'arbitrary discretion' " to the courts); *Hecht* v. *Bowles*, 321 U.S. 321, 329 (1944) (equity is "the instrument for nice adjustment and reconciliation between the public interest and private needs"). Such standards do not become lawless when applied to fact-based administrative agency determinations. *See Arizona Grocery Co.* v. *Atchison T. F. & S. Ry.*, 284 U.S. 370, 384-85 (1932) (describing shift of determination of reasonableness of railroad rates from courts to administrative agencies).

[10] *Cf. Daubert* v. *Merrell Dow Pharms, Inc.*, 509 U.S. 579, 593 (1993) (citing Jasanoff regarding issues of reliability of scientific evidence).

326 (D.C. Cir. 1991); Jasanoff, *supra*, at 94 (regulators draw conclusions that "involve subjective judgment, and even policy, to compensate for the absence of hard knowledge"). When regulators issue rules, "[t]hough the answer may be couched in technical terms, as a verdict about the adequacy of evidence, it necessarily incorporates a sociopolitically colored judgment about the acceptability of risk." *Id.* at 232; see also Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 Colum. L. Rev. 1613, 1617 (1995). The uncertainties inherent in regulatory science are particularly acute as administrative agencies push for the "last 10 percent" of environmental protection. See Stephen A. Breyer, *The Vicious Cycle* 11 (1993).[11]

This case amply demonstrates that proposition. The massive scientific uncertainties about the existence of any health effects from fine PM are uniformly acknowledged (by the President, Congress, CASAC, the National Academy of Sciences, and EPA itself), and Congress had appropriated large sums for further research with the express intent that EPA delay further rulemaking. Hatch/Bliley Br. 2-3; see also Pub. L. No. 105-178, §§ 6101-6104, 1998 U.S.C.C.A.N. (112 Stat.) 107, 463-65 (1998) (codified at 42 U.S.C. § 7407 note)

[11] The *Lead Industries* problem has thus become more important than ever before. While the air has gotten much cleaner under existing and past standards, Office of Air Quality Planning and Standards, EPA, *National Air Quality and Emissions Trends Report, 1998*, at 1, *at* http://www.epa.gov/oar/aqtrnd98 (last modified June 2, 2000), the country is still far from attaining the current NAAQS. Now, EPA is arrogating to itself the power to make arbitrary policy choices imposing dramatic costs on society without considering all relevant factors. This Court should not be swayed by arguments that Congress's enactment of procedural improvements in the NAAQS process obviates the need for close scrutiny of *Lead Industries* under the nondelegation doctrine. *See* Mass. Br. 36-38. The issue here is to vindicate the congressional mandate that the Administrator apply the *full* range of her expert judgment, based on *all* relevant circumstances, to set standards requisite to protect the public health.

(delaying implementation of revised NAAQS to allow for judicial review, and disclaiming ratification of those standards). For ozone, CASAC has declared that no "bright line" distinguishes any of the contemplated standards from any others in terms of health protection provided. Letter from George Wolff, Chair, CASAC, to Carol Browner, Administrator, EPA 3 (Nov. 30, 1995) (regarding CASAC closure on the primary standard portion of the Staff Paper for ozone). See *infra* at 26-29 (discussing EPA's reliance on indeterminate science). Indeed, the Administrator admits she is exercising "policy judgment," National Ambient Air Quality Standards for Particulate Matter; Final Rule, 62 Fed. Reg. 38,651, 38,668 (1997) ("*PM Rule*"); National Ambient Air Quality Standards for Ozone; Final Rule, 62 Fed. Reg. 38,855, 38,863, 38,867 (1997) ("*Ozone Rule*"), but maintains the fiction that her judgment is science-based, even though the setting of standards "necessarily" involves (and historically has involved) sociopolitical considerations such as cost. Jasanoff, *supra*, at 104-06, 232. EPA's stance aside, the nondelegation doctrine demands that the statute be interpreted in light of its context: *i.e.*, to give EPA intelligible principles by which to navigate extreme scientific uncertainty.

The second critical element of context that distinguishes other nondelegation cases is the sheer scope of the coercive power in the Administrator's hands here. The authority to set NAAQS is the power to dictate massive regulation of multitudinous sources by States and their political subdivisions in devising implementation plans under section 110. It is also undisputed, even by EPA's conservative estimate, that many billions of dollars in *annual* compliance costs, above and beyond what is required to meet current NAAQS, turn on every fractional change in the NAAQS. The plurality decision in *Industrial Union* recognized that the grant of vast power to an agency increases the risk of arbitrary action. 448 U.S. at 645-46. The court below likewise properly recog-

nized that such vast power demands a " 'more precise' " standard to ensure against arbitrary administrative action. Pet. App. 12a.

Thus, Judge Silberman, in his dissent from denial of rehearing en banc, was wrong to dismiss the nondelegation reasoning in *Industrial Union* as "a makeweight, tossed into the analysis, ... to help justify the result." Pet. App. 93a. First, nondelegation was central to the outcome of that decision, and justified the narrow construction adopted by the plurality. Second, because it interpreted the statute to ensure that the grant of power is not arbitrary in its context, *Industrial Union* is squarely within the tradition of this Court's nondelegation jurisprudence. Although not so much as mentioned in the Government's brief, that decision strongly supports rejecting *Lead Industries* in favor of a narrower construction. Indeed, the reasoning of *Industrial Union* applies *a fortiori* here, for EPA's power over the States and industrial sources under section 109 dwarfs that of OSHA to regulate hazardous workplaces.[12]

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[12] The Government is also wrong to fault the court of appeals for allegedly misusing the nondelegation doctrine as an improper "additional means, beyond the explicit judicial review provisions of the CAA, to supervise the exercise of administrative discretion." U.S. Br. at 26. The Government (and Judge Silberman, Pet. App. 95a-96a) contend that the court could do no more than undertake the arbitrary-and-capricious review authorized by statute. *See* 5 U.S.C. § 706; 42 U.S.C. § 7607(d)(9)(A). However, the constitutional prohibition on grants of arbitrary (*i.e.*, legislative) power to executive agencies is neither coextensive with, nor satisfied by, arbitrary-and-capricious review. The former ensures that the statute itself does not grant arbitrary power to an agency; the latter addresses the narrow question of whether, in a specific instance, the agency has acted arbitrarily in exercising properly delegated power. Here, the court of appeals was thus not seeking "to supervise the exercise of administrative discretion" in implementing the Act, but to ensure that the constitutional limits on congressional allocation of federal power are respected in the Act itself. This was a proper subject of review.

In short, the nondelegation doctrine requires this Court, if possible, to adopt a constitutional construction of section 109 of the Clean Air Act that ensures that the EPA's discretion is not arbitrary, given the statutory context of deep scientific uncertainty about health effects and unparalleled administrative power over the States and the national economy. *Lead Industries* cannot fit that bill: it authorizes the Administrator to rely solely upon scientific evidence even when science is indeterminate, thus leaving the Administrator free to set risk levels without any constraining principle.

II. THE *LEAD INDUSTRIES* INTERPRETATION OF SECTION 109 DOES NOT PROVIDE AN INTELLIGIBLE PRINCIPLE CONSTRAINING THE ADMINISTRATOR'S POWER.

A. Under A Proper Interpretation Of Section 109, The Principle Of Cost-Effectiveness Constrains The Administrator's Discretion When The Scientific Evidence Is Indeterminate.

Properly interpreted, section 109 of the Clean Air Act is clearly constitutional. As described more fully in our prior brief, Congress legislated "as far as was reasonably practicable," *Buttfield*, 192 U.S. at 496, in a scientifically complex area of environmental regulation, and channeled the Administrator's discretion by providing principled constraints that permit the courts to "ascertain whether the will of Congress has been obeyed," *Yakus*, 321 U.S. at 426. For pollutants emitted from numerous or diverse sources that "cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare," 42 U.S.C. § 7408(a)(1)(A), the Administrator, among other things, sets primary NAAQS "the attainment and maintenance of which in the judgment of the Administrator, based on [air quality] criteria and allowing an adequate margin of safety, are requisite to protect the public health." *Id.* § 7409(b)(1).

Congress intended the Administrator's judgment to be based on science to the extent possible: not only does section 109 require the Administrator to base the standard on air-quality criteria that "shall accurately reflect the latest scientific knowledge" regarding pollution effects, *id.* § 7408(a)(2), but it also authorizes "an independent scientific review committee," CASAC, to advise the Administrator on the establishment and revision of NAAQS, *id.* § 7409(d)(2)(A)-(B).

As noted above, science cannot alone guide the Administrator in her judgment. Recognizing the inherent indeterminacy of science about public health risks from pollution, and intending standards that would be "preventative or precautionary," H.R. Rep. No. 95-294, at 49 (1977), Congress directed the Administrator to "allow[] an adequate margin of safety" to account for scientific uncertainty in making a "judgment" about what is "requisite to protect the public health." 42 U.S.C. § 7409(b)(1). Congress did not forbid the Administrator to consider any factor relevant to inform her judgment as to what was "adequate" or "requisite"—and certainly did not preclude consideration of cost/benefit balancing, which is fundamental to traditional concepts of environmental risk management, Hatch/Bliley Br. 20-23, and of "protect[ing] the public health," see Br. for Cross-Pet'rs 37-43. To the contrary, Congress directed the Administrator to gather "information on air pollution techniques" that "shall include data relating to the cost of installation and operation, energy requirements, emission reduction benefits, and environmental impact of the emission control technology," 42 U.S.C. § 7408(b)(1), and to publish this information along with the air-quality criteria prior to the proposal of a new or revised NAAQS, *id.* § 7409(a)(2). Congress further required CASAC to "advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards,"

id. § 7409(d)(2)(C)(iv),[13] and required the Administrator to explain any significant departure from "pertinent findings, recommendations, and comments" of CASAC and the National Academy of Sciences, *id.* § 7607(d)(3). The Administrator also must conduct cost-benefit analysis of the NAAQS. *Id.* § 7612(a)(1).[14]

The regulatory scheme essentially replicates that of the Air Quality Act of 1967, except that the authority to set air-quality standards is now vested in EPA rather than the States: standards must be set at or below the level at which science reflected in the air-quality criteria shows dangers to public health, but, in the face of scientific uncertainty, the ultimate standard would reflect a socioeconomic judgment as to what risk levels are tolerable. See Hatch/Bliley Br. 15-18. Thus, scientific evidence of a significant risk of danger to the public health, and, to the extent science is uncertain, the cost-effectiveness of alternative standards, are the intelligible principles that constrain the Administrator's discretion.

Bound by *Lead Industries*, the court of appeals could not adopt this interpretation, Pet. App. 15a, and thus was compelled to declare unconstitutional the Administrator's construction (which itself was tethered to *Lead Industries*).

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[13] Despite the obvious intent of Congress, the court below accepted the Government's argument that information gathered in section 109(d)(2)(C) may not be used in setting NAAQS. Pet. App. 21a. Not only does that argument have no basis in text, but EPA does not follow it. Indeed, it explicitly relied on evidence gathered under subsection (C)(iii)—namely, the proportion of pollutant concentrations that is anthropogenic—in setting the ozone NAAQS. *Ozone Rule*, 62 Fed. Reg. at 38,868. Having done so, it cannot plausibly argue that it is barred from considering the cost data gathered under subsection (C)(iv) of that statute.

[14] EPA also considers costs in apportioning burdens among states pursuant to its authority to order upwind states to curtail emissions that contribute significantly to nonattainment by downwind states—a risk-management task that cannot be divorced from the setting of NAAQS. *See* Hatch/Bliley Br. 24-25.

Id. at 11a. The interpretation discussed above is not only the most natural reading of the Act's text, structure, and history, but it is also compelled by the doctrine of avoidance of constitutional questions: only cost-effectiveness and the balancing of benefits and costs are intelligible principles to guide the Administrator in choosing among alternatives that protect the public in varying degrees. Cf. *id.* at 14a-15a (cost-benefit analysis provides determinacy to avoid nondelegation problems); *International Union, UAW* v. *OSHA*, 938 F.2d 1310, 1319-21 (D.C. Cir. 1991) (same). By contrast, the Government's approach of simply identifying evidentiary factors for consideration does not provide any comparative standard whatsoever, and thus arrogates to the Administrator an impermissible power, legislative in nature, to draw lines on an arbitrary basis.

B. The *Lead Industries* Rule That EPA May Only Rely Upon Scientific Factors Even When Science Is Indeterminate Violates Nondelegation Principles.

Drawing on some of the same statutory provisions discussed above, the Government and its supporters attempt to defend *Lead Industries* by arguing that there are intelligible principles that bind the Administrator, even if cost-effectiveness may not be considered. Their view, summarized, is that EPA has a statutory mandate to "protect the public health" by setting standards, after consideration of air-quality criteria and CASAC advice and adding a margin of safety, that protect sensitive populations from adverse health effects linked to the presence of a criteria pollutant in the outside air. U.S. Br. 22-25; Mass. Br. 28-34. This, they claim, is specific enough to pass constitutional muster.

Erroneous as a matter of statutory interpretation, this construction cannot provide the "primary standard," *Buttfield*, 192 U.S. at 496, against which EPA's actions can be

measured. The reason is that EPA has acknowledged that section 109 does not require the NAAQS to eliminate all adverse health effects (*i.e.*, achieve zero-risk). See, *e.g.*, *PM Rule*, 62 Fed. Reg. at 38,653; *Ozone Rule*, 62 Fed. Reg. at 38,857. In other words, the purported "primary standard" of protecting against adverse health effects upon sensitive populations does not suggest any intelligible principle to guide the Administrator in deciding *which* adverse health effects to prevent, or *which* populations to protect. Moreover, all the statutory procedures on which their briefs rely only relate to that part of the NAAQS process that is not in controversy: namely, the congressional directive that NAAQS be based on the best science possible. The procedures do not address the issue of how the Administrator makes the highly consequential choice among alternative risk levels when the science is indeterminate, and when adverse health effects would still occur even under the alternatives selected. The lengthy recounting of statutory procedures in the opposing briefs thus should not deflect this Court's attention from the issue at hand: namely, as the court of appeals rightly identified it, what "intelligible principle" controls the discretion of the Administrator in choosing any risk level above zero when science does not provide the answer. Pet. App. 6a.

On this score, the Administrator offers only a series of so-called decisional factors, and it is on these factors that the validity of *Lead Industries* turns. The Administrator identifies those factors as "the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, the types of health information available, and the kind and degree of uncertainties that must be addressed." *Ozone Rule*, 62 Fed. Reg. at 38,883. But, those factors (though certainly relevant) are not "determinate criteria for drawing lines" and "do not themselves speak to the issue of degree." Pet. App. 6a, 7a. More fundamentally, in simply identifying decisional factors, the Administrator has failed in her obligation "to

apply *some* limiting standard, rationally related to the goals of the Act." *Iowa Utils. Bd.*, 525 U.S. at 388.

The nub of the issue is this: Because Congress did not expect NAAQS to eliminate all health risks, as EPA acknowledges, the setting of NAAQS is essentially an exercise in the allocation of environmental health protections and the management of risk. See Pet. App. 16a-17a (suggesting that EPA could derive intelligible principle from Oregon plan for rationing health care); Breyer, *supra*, at 18-19, 23 (discussing impact of finite resources on risk regulation). Put another way, EPA has set standards at levels that will protect some populations from health impairment, but not others. The only reason for drawing such lines is economic, in the broad sense of that word: namely, tighter standards are progressively expensive, and approaching zero risk is counter-productive because it diverts society's resources away from other needs. See, *e.g.*, H.R. Rep. No. 95-294, at 127 (1977) (rejecting argument that NAAQS could be set at a zero-risk level because such an approach "ignores all economic and social consequences and is impractical"). Cost-effectiveness is an intelligible principle by which to allocate health protection: if the scientific basis for choosing among various standards is indeterminate, the Administrator may select a standard because its benefits for the public are in her judgment reasonably commensurate with the costs to society.[15]

The medical-evidence decisional factors forwarded by the Administrator, by contrast, provide no principled basis for balancing and line-drawing. They are not rationally related to any coherent standard for allocating public health protections, nor do they fully "tak[e] into account the objectives of the

[15] *See* Alon Rosenthal et al., "*Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals*," 19 Ecology L.Q. 269, 336 (1992) (cost-effectiveness is a means "to maximize public health protection through the rationing of finite resources").

Act," *Iowa Utilities Board*, 525 U.S. at 392, which are to induce "reasonable Federal, State, and local governmental actions," 42 U.S.C. § 7401(c), to "promote the public health and welfare and the productive capacity of [the Nation's] population," *id.* § 7401(b)(1). EPA's exclusive reliance on such factors is feckless when the judgment regarding rationing of health protection is not merely technical, but social, political, and economic, see Jasanoff, *supra*, at 232. Indeed, no rational regulator would forbear from protecting any population—or any individual—from even a health effect of moderate severity, no matter the certainty of the evidence, if the cost of doing so were comparatively trivial. Breyer, *supra*, at 65; Cass R. Sunstein, *Is The Clean Air Act Unconstitutional?*, 98 Mich. L. Rev. 303, 308 (1999). Thus, in setting NAAQS at a certain level of protection above zero (achievable) risk, the Administrator has necessarily determined (without saying) that additional protections are not worth it.

The Government will no doubt claim in reply that broadening the factors EPA may consider to include costs necessarily expands its discretion, and thus heightens any nondelegation problems. That is not so, and this Court directly rejected such an argument in the *NBC* case, where it refused to narrow the Federal Communications Commission's authority under the "public interest" standard to the consideration of "technological objections to the granting of a license." 319 U.S. at 216. Such factors, the Court held, would be indeterminate in the context of radio regulation, given the evident purposes of the Communications Act of benefiting the public at large: "If the criterion of 'public interest' were limited to such matters, how could the Commission choose between two applicants for the same facilities, each of whom is financially and technically qualified to operate a station?" *Id.* at 216-17.

The same is true here; just as withdrawing relevant factors from the FCC's consideration would thwart protection of "public interest," so too would withdrawing consideration of costs and other regulatory effects of a NAAQS unduly limit the Administrator in achieving her mandate of protecting the public health.[16] Permitting the Administrator to consider costs does not increase her discretion; it simply prevents arbitrariness, and administrative charades, in selecting among alternative standards, and tethers her decisionmaking to statutory purposes, which is the overriding purpose of the nondelegation doctrine. And it promotes the accountability that is the animating reason for the nondelegation doctrine, see *Loving*, 517 U.S. at 757-58, by permitting meaningful judicial, congressional and public scrutiny of these enormously important administrative decisions.

By identifying indeterminate decisional factors as the only limits on its authority, EPA has arrogated to itself the arbitrary power to drive health risks all the way down to zero,

[16] Because "requisite to protect the public health" is the ultimate statutory standard, we emphasize that cost-effectiveness is not a straitjacket, and does not demand that the Administrator set the NAAQS at the precise point where benefits exceed costs. As the Government rightly contends, the nondelegation doctrine does not require quantitative "rules of thumb," *American Power & Light*, 329 U.S. at 106, and "[t]he difficulty or impossibility of drawing a statutory line is one of the reasons for supplying merely a statutory guide." *Sunshine Anthracite Coal*, 310 U.S. at 399-400. Cost-effectiveness is a decisional principle that can be weighed against the extent and uncertainty of health risks to ensure administrative judgment that rationally protects public health, and that would then be reviewable by courts under the arbitrary and capricious standard. It is a more flexible standard than other possible constraining principles: *e.g.*, a mandate for the Administrator to reduce health risks to the level of technological or economic feasibility. Here, the Administrator has the latitude to go beyond feasibility constraints if the public health benefits warrant, *see Union Electric Co.* v. *EPA*, 427 U.S. 246, 257 (1976) (discussing technology-forcing character of Act), or to stop short of feasibility if the anticipated health benefits are not worth the cost.

even if that would bring the entire economy to its knees. In charging EPA with setting standards "requisite to protect the public health," Congress cannot be presumed to have given EPA the unfettered power to impose mandates that may be wholly inimical to the public interest.[17]

Thus, just as this Court in *Iowa Utilities Board* interpreted the local competition provisions of the Telecommunications Act of 1996 to "requir[e] the [FCC] to determine on a rational basis *which* network elements must be made available [to competitors], taking into account the objectives of the Act," 525 U.S. at 391-92, so too this Court should interpret section 109 to require EPA to determine on a rational basis *which* populations will be protected in setting NAAQS. Because the allocation of public health protections in managing risks is, in the face of scientific uncertainty, a socioeconomic and political decision, the consideration of economic factors must play some part in any rational decisionmaking by EPA. *Lead*

[17] This Court has recognized that the resources of American society for achieving important social objectives "are limited, and therefore precious; they cannot be left to wasteful use without detriment to the public interest." *NBC*, 319 U.S. at 216, 217. Finite resources are an inescapable fact of environmental regulation, just as they are in the field of health care, where priority-setting is inevitable. *See, e.g.*, Leonard M. Fleck, *Just Health Care Rationing: A Democratic Decisionmaking Approach*, 140 U. Pa. L. Rev. 1597 (1992). The aggregate (*i.e.*, "political") level of expenditures American citizens, governments, and businesses make available toward public health is a precious resource. Accordingly, "*comparative* considerations as to the [benefits] to be rendered," *NBC*, 319 U.S. at 217 (emphasis added), must govern here. EPA thus sheds a crucial limit on its administrative power by failing to compare the significance of health risks—as in *Industrial Union*—and the relative "wasteful[ness]" of regulatory options—as in *NBC*. The President understood this in issuing the cost limitations on implementation of the NAAQS, but his effort to effect a cure was neither timely nor legally sufficient. Hatch-Bliley Br. 27-30. EPA had to apply the requisite limiting principles when it set the NAAQS.

Industries, by excluding such considerations, offers in their place nothing but radical indeterminacy and unconstrained discretion on the part of the Administrator.

C. The Arbitrariness Of The *Lead Industries* Rule Is Evident In The PM And Ozone Rulemakings.

The incoherence of the decisional factors that the Government claims are "intelligible principles" is manifest in the PM and ozone rulemakings. This incoherence is not the product of the Administrator's abuse of a proper discretion, but of a statutory misconstruction of the Act that yields no standards rationally related to the statutory task of setting NAAQS.

1. *PM Rulemaking*

In the PM rulemaking, the Administrator applied the decisional factors and purported to have set the $PM_{2.5}$ standard by relying on studies with "statistical significance to the 95% confidence level." U.S. Br. 32. According to the Government, the Administrator picked the lowest concentration at which an epidemiological study showed a statistically significant correlation between PM and an adverse health effect, and added a margin of safety. *Id.* at 32-33.

If this were so, it would be about as arbitrary an approach to multibillion-dollar decisions regarding the public health as could be imagined. As an initial matter, it is at least ironic that EPA is trumpeting statistical significance as the dispositive factor even as it is criticized for downplaying that factor in other risk-management contexts. See Michael Gough & Steven Milloy, *EPA's Cancer Risk Guidelines: Guidance To Nowhere*, Cato Policy Analysis No. 263 (Nov. 12, 1996), *available at* http://www.cato.org/pubs/pas/pa-263.html. Furthermore, even if lack of statistical significance

may be reasonable grounds for rejecting a study,[18] it by no means follows that statistical significance can reasonably be the principal basis for regulatory action. First, statistical significance indicates that the results are not the product of chance, but it does not measure "the extent or importance of a difference" detected by the study or "the strength or importance of an association" between two variables (*e.g.*, a pollutant exposure and a health effect). David H. Kaye & David A. Freedman, *Reference Guide on Statistics*, *in* Federal Judicial Ctr., *Reference Manual on Scientific Evidence* 331, 378-79 (1994). Second, statistical significance (which is often simply a function of sample size, *id.* at 379) assumes the validity of the study design and the randomness of the sampling, among other factors; worthless studies may generate statistically significant results. *USGS Site*, *supra*, at 1, 3-4. Finally, EPA's reliance on this single factor is absurd given its overall conclusion that the scientific evidence on PM is rife with "significant uncertainties," *PM Rule*, 62 Fed. Reg. at 38,655—including the fundamental uncertainty as to whether particles of a certain size are causing *any* health effects, or whether those detected result instead from other factors (such as a specific chemical agent). See Br. for Cross-Pet'rs at 13-15. No regulator worth her salt would make decisions on this basis, and it is doubtful the Administrator did so here. This is more likely yet another science charade—the invocation of technical jargon to support a decision made on other, undisclosed factors.[19]

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[18] But *cf.* Douglas H. Johnson, *The Insignificance of Statistical Significance Testing*, 63 J. of Wildlife Mgmt. 763 (1999), *available at* http://www.npwrc.usgs.gov/resource/1999/statsig/stathyp.htm ("*USGS Site*") (discussing longstanding controversy among scientists over whether statistical significance has any utility in scientific research).

[19] It is noteworthy that EPA disregards good science when it conflicts with the agency's preferred policy, *see Chlorine Chemistry Council* v. *EPA*, 206 F.3d 1286, 1291 (D.C. Cir. 2000) (criticizing "EPA's disregard of its own scientific findings"); *Chemical Manufacturers Ass'n* v. *EPA*, 28

2. *Ozone Rulemaking*

The Government defends the ozone rulemaking with the *ipse dixit* that EPA "identified important and meaningful differences in the character of the scientific evidence regarding risks," U.S. Br. 33, but it is clear that EPA engaged in arbitrary linedrawing. For ozone, the evidence indicated that 41,000 children in nine urban areas would suffer moderate or severe pain on deep inspiration once or more per year at a concentration of .09 parts per million ("ppm"); 27,000 children would at the new NAAQS of .08 ppm; 22,000 would at .08 ppm with a slightly lower average daily maximum; and approximately 9,000 would at .07 ppm. Similarly, 97,000 children would suffer large lung-function decreases of at least 20% at .09 ppm; 58,000 at the new NAAQS of .08 ppm; 43,000 at .08 ppm with a slightly lower average daily maximum; and approximately 12,000 at .07 ppm.[20]

F.3d 1259, 1266 (D.C. Cir. 1994) (criticizing EPA's scientific " 'let-them-eat-cake' attitude" to the public it serves); *Flue-Cured Tobacco Cooperative Stabilization Corp.* v. *EPA*, 4 F. Supp. 2d 435, 456, 460 (M.D.N.C. 1998) (criticizing EPA for cherry-picking data and altering methodology to achieve statistical significance), but happily relies on bad science that may support favored policy outcomes. *See also* Phillip K. Howard, *The Death of Common Sense* 7 (1994) (noting instance where EPA set a rule that maximized cost without any corresponding benefit, and the counterproductive results of such regulation).

[20] *Ozone Rule*, 62 Fed. Reg. at 38,865; R.G. Whitfield, *A Probabilistic Assessment of Health Risks Associated With Short-Term Exposures to Tropospheric Ozone: A Supplement* 21-22 (Jan. 1997) (6 Ozone JA 2325, 2352-53) (prepared for EPA); National Ambient Air Quality Standards for Ozone; Proposed Decision, 61 Fed. Reg. 65,716, 65,725 (1996) (0.07 ppm). The figures used for the .08 and .09 ppm standards are drawn from EPA's final rule, which did not repeat the risk analysis for the 0.07 ppm alternative standard that was included in the proposed rule. While the original and final risk assessments used slightly different methodologies, they show roughly similar disparities in health effects. *See* 61 Fed. Reg. at 65,725.

On what basis did EPA decide to provide protection from severe pain on inspiration to an incremental 14,000 children by setting the NAAQS at 0.08 ppm, but not to another 18,000 by setting it one notch lower at 0.07 ppm? Why did EPA protect an incremental 39,000 (but not an additional 46,000) children from large lung-function decreases? EPA's decisional factors do not supply a standard—these are the *same* populations suffering the *same* health effects, estimated from the *same* data and models, with the *same* uncertainty for any concentration. The only rational, moral, and democratic reason why EPA would draw a line at .08 ppm and deny improved health to many thousands of people is that the massive expenditure of national resources required to drive ozone concentrations that low would be counterproductive for the overall health of the public.

Congress fully intended for the Administrator to consider the cost-effectiveness of alternative standards in the face of scientific uncertainty. "The language of the Act does not withdraw such a [consideration]" from the Administrator's judgment, "and there is no evidence that Congress did not mean its broad language to carry the authority it expresses." *NBC*, 319 U.S. at 218. As the court below acknowledged, Pet. App. 15a, cost-effectiveness of a precautionary standard is an intelligible principle where the scientific evidence is indeterminate—indeed, it is the generally accepted principle of risk management and line-drawing in the face of scientific uncertainty. See Hatch/Bliley Br. 7-8. Moreover, it is a principle which the judiciary can enforce to determine whether congressional will has been obeyed, *Yakus*, 321 U.S. at 426, and such considerations must be out in the open for the judiciary to determine whether the Administrator has substantially complied with the statute.[21]

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[21] Judicial review is an indispensable concomitant of broad delegations by Congress, *see American Power & Light*, 329 U.S. at 105, and necessary to the proper implementation of the Clean Air Act. Contrary to

Lead Industries offends nondelegation principles; it gives EPA arbitrary unilateral power to overhaul the nation's environmental policy, and transform the nation's economy dramatically, without a congressional mandate or scientific imperative to do so. This Court should construe section 109 to permit the Administrator to consider the cost-effectiveness of alternative air-quality standards,[22] and this Court should adopt that interpretation to avoid serious questions about the statute's constitutionality.

CONCLUSION

On the grounds set forth above, the judgment below should be affirmed.

Respectfully submitted,

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September 11, 2000

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the Government's contentions, U.S. Br. 27, judicial review is more important, not less, when the agency engages in regulatory science. The principle of deference to agency scientific decisions established in *Baltimore Gas & Electric* v. *NRDC*, 462 U.S. 87, 103 (1983), is not to the contrary; it simply means that the court cannot substitute its judgment for that of the agency. Courts nonetheless still have an important role to ensure reliable regulatory science, similar to the gatekeeping function of trial courts recognized in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Here, if *Lead Industries* is set aside, a reviewing court could prevent EPA from withholding its scientific assumptions, papering over scientific uncertainties, and failing to consider all "the relevant factors." *Motor Vehicle Mfrs. Ass'n of United States, Inc.* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Courts must be vigilant in unmasking science charades, wherein an agency dresses its unadorned policy choices in scientific garb.

[22] It is the function of this Court, not EPA, to interpret the statute to define intelligible principles. *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837 (1984), is inapposite to nondelegation issues. *Chevron* is premised on congressional intent to delegate rulemaking power to the agency. *See FDA* v. *Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291, 1314 (2000); *Chevron*, 467 U.S. at 844-45. A delegated power cannot be invoked to supply the principles that make the very delegation constitutionally permissible. The Constitution requires that the limiting principle must come from the statute itself, as construed by the judiciary.